8.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

FEB 17 2010

The submitter of this premarket notification is:
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This revised summary was prepared on August 14th, 2009.

8.1 Device Names

The names of the devices are the Philips Avalon Fetal Monitors FM20, FM30,FM40 and FM50. Classification names are as follows.

Device Panel	Classification	ProCode	Description
Obstetrical and Gynecological Monitoring Devices	§884.2660, II	MAA HEL HEK KNG	Fetal ultrasonic monitor and accessories
	§884.2675, II	HGP	Fetal scalp circular (spiral) electrode and applicator
	§884.2700, II	HGS KXO HFO HFN	Intrauterine pressure monitor and accessories
	§884.2720, II	HFM	External uterine contraction monitor and accessories
	§884.2740, II	HGM	Perinatal monitoring system and accessories
	§884.2960, II	HGL	Obstetric ultrasonic transducer and accessories
Circulatory System Devices	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector

8.2 Subject devices

The subject devices Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 are substantially equivalent to the previously cleared Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 marketed pursuant to K052795, K062137 and K071800.

The subject devices Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 are a modification of the legally marketed Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 and offer monitoring of fetal heart rates, fetal movement profiles, fetal Direct ECG, maternal uterine activity, maternal heart rates, maternal pulse rates, maternal ECG, maternal non-invasive blood pressure (NIBP) and maternal oxygen saturation (SpO2) during antepartum testing and labor and delivery.

8.3 Modifications

The modification of the Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 only permits specific SpO2 sensors, which are already cleared for the Philips picoSATIIplus SpO2 pulse oximetry module, the Philips Intellivue X2 (M3002A) multi measurement module and the Philips M1020B SpO2 plug-in module, to be also used with the Philips Avalon Fetal monitors FM30, FM40 and FM50.

8.4 Intended Use

The modified devices have the same intended use as previously cleared for the legally marketed predicate devices Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 (K052795, K062137 and K071800).

Intended Use: The Philips Avalon FM20, FM30, FM40 and FM50 Fetal/Maternal Monitors are intended for non-invasive monitoring of the physiological parameters of pregnant women during antepartum testing and labor and delivery.

All monitors are intended for monitoring fetal and maternal heart rates, fetal movement profiles, maternal pulse rates, uterine activity, maternal noninvasive blood pressure, and additionally for the FM30, FM40 and FM50 maternal oxygen saturation (SpO2).

The FM30 and FM50 are additionally intended for maternal ECG and for invasive monitoring of fetal Direct ECG and intrauterine pressure.

All monitors are intended for generating alarms from fetal and maternal parameters, for displaying, storing and recording patient data and related waves, transmitting patient data to a patient information and surveillance system on a network, and for postpartum monitoring of the mother.

All monitors are intended for use by trained health care professionals.

They are intended for use in labor and delivery rooms, antepartum testing areas and during postpartum recovery in the hospital environment. They are not intended for use in intensive care units or operating rooms. The FM20 and FM30 are additionally intended for use in healthcare facilities outside hospitals, for example in doctors' offices, and in private households.

Contraindications: All monitors are NOT intended for:
- use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI).
- ECG measurements on patients connected to external electrical stimulators or with cardiac pacemakers.
- use with the IUP/ECG patient module (M2738A) in domestic establishments and those connected directly to the public low-voltage supply network that supplies buildings used for domestic purposes.

The before is the same intended use as previously cleared for the Philips Avalon Fetal Monitors FM20, FM30, FM40 and FM50 (K052795, K062137 and K071800). The intended use of the FM40 and FM50 is a subset of the intended use of the FM20 and FM30.

As a summary, the following table provides an overview about the monitored parameters per fetal monitor.

	Philips Avalon Fetal Monitors			
Monitored Parameters	FM20	FM30	FM40	FM50
Up to three Fetal Heart Rates (FHR) via ultrasound (US)*	Yes	Yes	Yes	Yes
Single Fetal Heart Rate via direct ECG (DFHR)*	--	Yes	--	Yes
Fetal Direct ECG (DECG)	--	Yes	--	Yes
Fetal Movement Profile	Yes	Yes	Yes	Yes
Uterine activity via external Toco	Yes	Yes	Yes	Yes
Uterine activity via intrauterine pressure (IUP)	--	Yes	--	Yes
Pulse oximetry (maternal SpO2)	--	Yes	Yes	Yes
Maternal Pulse Rate	Yes	Yes	Yes	Yes
Maternal Heart Rate (MHR) via maternal ECG	Yes	Yes	Yes	Yes
Maternal ECG (MECG)	--	Yes	--	Yes
Non-invasive blood pressure (NIBP),	Yes	Yes	Yes	Yes

*: A maximum of three fetal heart rates can be monitored (including max. one DECG)

8.5 Technological Characteristics

The subject devices Philips Avalon Fetal Monitors FM30, FM40 and FM50 have the same technological characteristics as the legally marketed predicate devices Avalon Fetal Monitors FM20, FM30, FM40 and FM50.

8.6 Verification and Validation

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and regression tests as well as testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the Philips Avalon Fetal Monitors meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Silver Spring, MD 20993-0002

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GERMANY

FEB 17 2010

Re: K092028
Trade Name: Philips Avalon Fetal Monitors, model FM20, FM30, FM40 and FM50
Regulation Number: 21 CFR §884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM
Dated: October 19, 2009
Received: October 22, 2009

Dear Mr. Asmalsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092028

Device Name: Philips Avalon Fetal Monitors
FM20(M2702A), FM30(M2703A), FM40(M2704A) and
FM50(M2705A).

Indications for Use:

Avalon Fetal Monitor FM20:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, non-invasive blood pressure, pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas and in private households.

Avalon Fetal Monitor FM30:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas and in private households.

Avalon Fetal Monitor FM40:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal Monitor FM50:
Indicated for use by trained health care professionals whenever there is a need for monitoring of the physiological parameters uterine activity, heart rate, ECG, oxygen saturation, non-invasive blood pressure, and pulse rate of pregnant women and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Prescription Use __Yes____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __No___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092028